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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,320

Applicant(s)

UPADHYAY, AJAY HASMUKHLA

Examiner

Lakshmi S Channavajjala

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-- *Th MAILING DATE of this communication appears on th cover she t with th correspondenc address --*
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 30-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt of request for extension of time, amendment A dated 4-22-03 and supplemental response dated 4-25-03 is acknowledged.

Claims 1-10 are pending. Claims 11-29 have been canceled. New claims 30-38 have been added.

The following rejection of paper # 6 has been maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,711,774 to Denick, Jr. et al (Denick).

Instant claim 1 is directed to a composition comprising guaifenesin and a binder and being in the form of particles, wherein less than about 30% by weight of the particles are greater than 425 micrometers in size and greater than about 80% by weight of particles are greater than about 45 micrometers. See above 112, 2nd paragraph rejection with respect to particle sizes claimed.

Denick discloses compositions containing guaifenesin mixed with magnesium aluminum silicate until a homogenous mixture is obtained (see example 1, in col. 11, lines 20-43). Magnesium aluminum silicate is used as an adsorbate for guaifenesin. Although Denick does not call it binder, it reads on instant binder because the term is broad and does not define any specific compound. Further, Denick discloses that the composition is dried and milled to produce a free

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flowing particulate material having a particle size of about 100 microns. Instant claim states less than 30% particles have a size greater than 425 microns, which includes 0%-30%. In other words, particles >425 microns are not required for the composition. Accordingly, the composition of Denick anticipates instant composition of claim 1.

Claim Rejections - 35 USC § 103

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,711,774 to Denick, Jr. et al (Denick).

Denick, discussed above, teaches a particulate composition comprising guaifenesin and magnesium aluminum silicate. Denick teaches that the particle size of the composition, upon milling to a free flowing composition, is about 100 microns (example 1). Further, Denick suggests that the particulate size ranging from 10 to 150 microns is suitable for the invention i.e., to prepare a guaifenesin composition containing magnesium aluminum silicate as an adsorbate. As explained above, instant claims do not specify any binder and accordingly, magnesium aluminum silicate of Denick reads on instant binder. Denick differs from the instant claims in the percentages of particle sizes. Instant Claim 5 requires 10-60 percent particles in the range of 45 to 150 microns; claim 6 requires > 10% particles having > 75 microns and > 55% particles having 45 microns; claim 7 requires < 25% exhibit a size range greater than 425 microns, 17%-55% particles are in a range of 45-150 microns and > 85% particles have > greater than 45 microns. It would be obvious for one of ordinary skill in the art at the time of the instant invention to choose and obtain guaifenesin composition having claimed particle sizes because Denick teaches that suitable particle sizes in the range of 10-150 microns are preferred for adsorbing sufficient quantities of medicament solution to prepare an acceptable drug product.

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Denick does not state the flow rate recited in claim 8. However, it is the position of the examiner that because Denick teaches particles in the same size range as required by the claims, optimizing the flow rate to produce a free flowing particulate formulation, having the claimed flow rate would have been obvious for a skilled artisan at the time of the instant invention.

Response to Arguments

Applicant's arguments filed 4-22-03 have been fully considered but they are not persuasive.

Denick (102 b):

Applicants argue that Denick does not indicate the magnesium aluminum silicate adsorbed on to guaifenesin is compressible into a compressed dosage form and that Denick teaches addition of sugars and other excipients for preparing a compressed tablet. However, instant claims do not recite the limitation of compression or compressible. Further, magnesium aluminum silicate has been recognized as a binder in several compositions (refer to the attached US patent No. 5,916,593). Applicants have not shown otherwise i.e., that magnesium aluminum silicate does not act as a binder. With respect to applicants' argument that claims 4, 9 and 10 are not disclosed by Denick, it is to be noted that instant rejection only includes claim 1 and claims 4, 9 and 10.

Denick (103 a):

Applicants traverse examiner's statement that although Denick does not teach the exact flow rate, because the particle size of Denick is in the same range, optimizing the flow rate to

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produce free-flowing particulates would have been within the scope of a skilled artisan.

Applicants argue that as explained in response to the anticipation rejection, the disclosure of Denick is deficient of a binder component of applicants' particulate guaifenesin composition.

Applicants also argue that examiner's explanation of particle size and flow rate are not relevant because the adsorbate of Denick is different from the composition of applicants' claimed particles. However, examiner directs applicants' attention to the reference attached to this office action (US 5,916,593) showing that magnesium aluminum silicate (also taught by Denick) is used as a binder. With respect to applicants' argument that the average particle size of Denick is 100, the rejection clearly explained the claimed particle sizes in different amounts, majority of which fall within the claimed range of 10-150 microns taught by Denick. Therefore, optimizing the particle size with an expectation to obtain art recognized effect would have been within the scope of a skilled artisan.

Applicant's arguments with respect to claims 1-10 as being obvious over Blume et al have been considered but are moot in view of the new ground(s) of rejection.

Claims 1-10 and 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,372,252 to Blume et al (hereafter Blume) in view of US 4,269,859 to Morse.

Blume teaches sustained release formulations comprising guaifenesin, a hydrophilic polymer such as hydroxypropyl methylcellulose, a water insoluble polymer and other tableting ingredients (col. 4, lines 4-28 and col. 6, lines 1-43). Among the pharmaceutical additives, Blume teaches lubricants such as magnesium stearate, calcium stearate etc; binders such as

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povidone (polyvinylpyrrolidone), gelatin, starch; glidants such as talc or silicon dioxide, stabilizers and other excipients such as lactose, sorbitol etc (col. 6, lines 45-65). Further, Blume teaches preparing the composition by granulation and compression (col. 8), which includes as one of the steps, drying and milling the composition and passing through sieves of 100 mesh screen size (col. 8, lines 20-25). Examiner notes that a 100-mesh size screen allows for particles of 150-micron size (see instant description on page 14). Blume does not teach the exact percentages of the particle sizes as claimed.

Morse teaches a method of tableting using cellulosic floc granules, which acts as a binder and a disintegrant, and which imparts good flow and binding characteristics. Morse teaches making tablets by direct compression involves three requisites: free-flowing particulate material, binding properties of the material and material that does not stick to punches or dies (col. 1). Further, Morse teaches that the cellulosic binding material should have an average particle size in the range of 20 and 55 microns or even 30 to 40 microns (col. 2 and col. 7). Further, Morse teaches that cellulose particles of the above size range impart a good flow properties (example 13) and adequate tablet hardness, binding strength and stability due to the flow rate and the binding properties for binding the tablet to itself (Col.8). Morse further suggests admixing the cellulosic floc with other pharmaceutical excipients such as starch, lactose, dextrose, mannitol, carboxymethyl cellulose; lubricants such as magnesium stearate, PEG and other excipients such as talc, silica, dicalcium phosphate (col. 8, lines 45-67), which are also described in the instant specification. Further, Morse also suggests that the amount of excipient, lubricant or binder should not be employed at such levels as to reduce the necessary and desirable free-flow characteristics of the cellulose granules themselves (col. 9). Accordingly,

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it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the appropriate particle sizes binders, disintegrants and such tableting aids in the guaifenesin containing composition of Blume because Morse teaches that free-flowing characteristics in a compressible tablet preparation is a function of particle size and that the free-flowing binder material (with a particle size of 30 to 55 microns) imparts the desired hardness, strength and stability to the tablet. Further, optimizing the amounts of binders, lubricants and other excipients in the guaifenesin comprising medicament formulation of Blume would have been within the scope of a skilled artisan because Morse suggests that the amounts of excipients should be such that the flow characteristics should not be affected.

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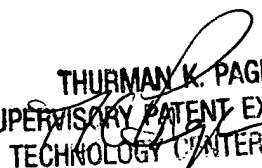
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
July 29, 2003



THURMAN K. PAGE
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